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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/804,589

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Marvin L. Boerboom

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FULBRIGHT & JAWORSKI L.L.P.
600 CONGRESS AVE.
SUITE 2400
AUSTIN, TX 78701

EXAMINER

FOX, DAVID T

ART UNIT

PAPER NUMBER

1638

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

02/26/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/804,589	Applicant(s) BOERBOOM, MARVIN L.	
	Examiner David T. Fox	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>30 September 2004</u> . | 6) <input type="checkbox"/> Other: _____ |

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Specification and Claim Objections

The specification is objected to on pages 26 and 50; and claims 1-2, 5, 8-9, 11, 14-16, 19-20 and 25 are objected to; for their inclusion of blank lines. It is assumed that the blanks will be replaced with the ATCC deposit accession number and date of deposit, or copending application serial number (on page 50), as appropriate. All specification amendments should comply with 37 CFR 1.121(b).

Indefiniteness.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-4, 14, 20-21 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Dependent claims are included in all rejections.

Claim 3 is indefinite in its recitation of "further defined as an essentially homogeneous population of seed" whose effect on the scope of the claim is unclear. The plain meaning of claim 2, on which claim 3 depends, is a homogeneous population of genetically identical inbred seed. Thus, the "essentially homogeneous" language would appear to be superfluous. However, reading the claims in light of the specification, lines 19-21 of page 5 indicate that inbred seed can form less than 100% of an essentially homogeneous population. Thus the scope of claim 3 is unclear. If claim 3 were amended to read ---An essentially homogeneous population of corn seeds

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consisting essentially of the inbred corn seed of claim 1---, the claim would have a definite meaning.

Claim 4 is indefinite in its recitation of "further defined as essentially free from hybrid seed" as its effect on the scope of the claim is unclear. Claim 2 from which it depends does not mention hybrid seed, and the plain meaning of that claim is a homogeneous population of inbred seed. Amending the claim to read ---A population of corn seeds consisting essentially of the inbred corn seed of claim 1, and essentially free from hybrid seed--- would obviate this rejection.

Claim 14 is indefinite in its recitation of "capable of", as it is unclear whether or not the corn plant does or does not actually express the physiological and morphological characteristics of the exemplified corn inbred, at any developmental stage or in any environment. Replacement of "is capable of expressing" with ---expresses--- would obviate this rejection.

Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the repetition of steps (c) and (d) for at least three generations.

Claim 20 is drawn to a method for producing a conversion of the exemplified corn variety, wherein "substantially all" of the alleles at each genetic locus of said conversion are from the exemplified corn variety. However, such a conversion plant is only possible if at least four generations of backcrossing to the original exemplified corn variety are carried out. It is well-known in the art that after two backcrosses (as

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currently claimed in part (e) of claim 20), as much as 12.5% of the donor parent (non-exemplified parent) genome remains; and that four backcrosses are required to reduce the amount of the donor genome to 3.125%. A corn plant that possesses as much as 12.5% of the non-exemplified corn variety's genome would not be a "conversion" plant as defined by Applicant. See also the paragraph bridging pages 3 and 4 of the specification; and page 27 of the specification, top paragraph.

Amendment of claim 20, part (e) to replace "one additional generation" with ---three additional generations--- would obviate this rejection.

Claim 21 is indefinite in its recitation of "genetic locus was stably inserted into a corn genome" which is confusing, as it is unclear whether the locus was inserted into the genome of the corn plant of claim 20, or some other corn plant, given the recitation of "a genome". Replacement of "a" with ---the--- would obviate this aspect of the rejection. Alternatively, replacement of the phrase "stably inserted into a corn genome by genetic transformation" with ---conferred by a transgene--- would also obviate this rejection.

Claim 23 is indefinite in its recitation of "yield enhancement", "improved nutritional quality", and "enhanced yield stability"; as "enhanced" and "improved" are relative terms which do not clearly specify the degree of trait expression. Deletion of these phrases from claim 23 would obviate this rejection.

All claim amendments should comply with 37 CFR 1.121(c).

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Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Deposit

Claims 1-26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel plants. Since the plant is essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the plant is not so obtainable or available, the requirements of 35 USC 112 may be satisfied by a deposit of the plant. A deposit of 2500 seeds of each of the claimed embodiments is considered sufficient to ensure public availability. The specification does not disclose a repeatable process to obtain the plant and it is not apparent if the plant is readily available to the public. It is noted that applicants intend to deposit the plant but there is no indication in the specification on page 26 as to public availability. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or

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condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
- (d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and,
- (e) the deposit will be replaced if it should ever become inviable.

Quantitatively Inherited Traits

Claim 23 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claim is broadly drawn to a method for introducing a single genetic locus of any sequence and from any source into a corn plant, which genetic locus confers "yield enhancement", "improved nutritional quality", or "enhanced yield stability". In contrast, no guidance is provided in the specification for the identification or evaluation of any genetic locus conferring any of these traits.

Traits such as "yield enhancement", "enhanced yield stability", or "improved nutritional content," are conferred by multiple genetic loci, i.e. are quantitatively inherited, wherein such traits are incorporated into a desired genetic background via molecular markers. However, the use of molecular markers in corn breeding is unpredictable. Goldman et al teach that the use of molecular markers to facilitate the identification of chromosomal regions associated with quantitatively inherited traits in corn is hampered by the different linkage maps generated when different breeding lines are used as parents (see, e.g., page 909, column 2, top paragraph; paragraph bridging pages 911 and 912; paragraph bridging pages 912 and 913). In addition, inconsistent results were observed regarding the correlation of particular quantitatively inherited traits (see, e.g., Goldman et al, page 910). Furthermore, quantitative traits such as oil or protein content are inversely proportional to kernel size in corn (see, e.g., Goldman et al, page 908, column 1, middle paragraph and column 2, bottom paragraph). Thus, breeding for improved nutritional quality would detrimentally affect yield improvement.

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to identify and isolate a multitude of non-exemplified single gene loci conferring yield

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enhancement, improved nutritional quality, or enhanced yield stability; and to evaluate the ability of these putative single genetic loci to function when introduced into the exemplified maize variety.

Amending claim 23 to address the indefiniteness rejection would obviate this rejection.

Written Description

Claim 23 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim is broadly drawn to a method for introducing a single genetic locus of any sequence and from any source into a corn plant, which genetic locus confers "yield enhancement", "improved nutritional quality", or "enhanced yield stability". In contrast, no guidance is provided in the specification for the identification or characterization of any genetic locus conferring any of these traits.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials. *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that

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material.≡ *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to visualize or recognize the identity of the members of the genus.≡ *Id.*

See MPEP Section 2163, page 156 of Chapter 2100 of the August 2001 version, column 2, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

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See also *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

See also *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

Amending claim 23 to address the indefiniteness and enablement rejections would obviate this rejection.

Anticipation

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by each of Hall (US 6,096,952) and Bradbury (US 5,936,145).

Claim 14 is drawn to a plant which is "capable of" expressing all of the physiological and morphological characteristics of the exemplified corn inbred. Claim 24 is drawn to a corn plant made by crossing the exemplified inbred plant to any other

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plant, including one of its parents, followed by backcrossing the product of this cross to the exemplified inbred; followed by at least one repetition of this process.

The instant specification teaches that the exemplified inbred has inbreds 01DHD16 and 87DIA4 as parents, wherein the exemplified inbred and parent inbreds share several traits and differ in several others (see, e.g., page 23, lines 17-19; Table 1, pages 25-26).

Hall teaches parent corn plant 01DHD16 which expresses the following morphological traits expressed by the exemplified corn inbred: straight internode, medium green leaves, green glume with absent glume band, semi-conical ear, short husk bract, green fresh husk and buff dry husk, and red cob (see, e.g., Table 4, columns 14-15).

Bradbury teaches parent corn plant 87DIA4 which expresses the following morphological traits expressed by the exemplified corn inbred: straight internode, medium green leaves, weak sheath anthocyanin, medium sheath pubescence, green glume and absent glume band, semi-conical ear, short husk bract, tight husk opening, a fresh husk color of green, a dry husk color of buff, red cob, and Dent kernel type (see, e.g., Table 4, columns 14-15).

Accordingly, each of Hall and Bradbury teaches a plant which is "capable of" expressing the morphological traits of the exemplified inbred, as claimed in claim 14. Furthermore, since claim 24 reads on a plant with a substantial amount of genetic information from either parent of the claimed inbred, each of Hall and Bradbury also teach such a plant.

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See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

See *In re Best*, 195 USPQ 430, 433 (CCPA 1977), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

Amending claim 14 to overcome the rejections under 35 USC 112, second paragraph, would obviate the above art rejection for this claim. Amending claim 20 to overcome the rejection under 35 USC 112, second paragraph, would obviate the above art rejection of claim 24.

Claims 1-9, 14-15 and 19 are rejected under 35 U.S.C. 102(b) based upon a public use or sale of the invention.

As admitted by Applicant on pages 3-4 of the Response filed 11 December 2006, two other maize varieties with the same parents as the instantly exemplified maize variety, namely 89DUD3 and 91DUD4, were publicly available or on sale at the time of filing of the instant application. Given their identical parentage, it is assumed that such plants anticipate the claimed maize variety. Furthermore, the maize plant regenerated from tissue culture as claimed in claim 14 would be indistinguishable from the original exemplified plant, and so is included in this rejection. See *Best* and *Thorpe* cited above.

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Applicant is invited to provide information which distinguishes the traits of each of 89DUD3 and 91DUD4 from the exemplified variety.

Claims 15 and 19 are included in this rejection because they read on self-pollination which would inherently occur in the fields in which the above corn plants were grown.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is 571-272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

February 15, 2007

DAVID T. FOX
PRIMARY EXAMINER
GROUP 480/1638

